



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 11, 1996

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: PP Nos. 4F4313/4H5687. Cyfluthrin (128831) on Citrus Agricultural Commodities/Food and Feed Processed Commodities. Petition Amendment Dated 2/3/95. D213306, D213307, D213792. Case Nos. 285467, 285468. CB Nos. 15312, 15313, 15361. MRID No. 430765-01.

FROM: Stephanie H. Willett, Chemist *SHW*
Tolerance Petition Section 2
Chemistry Branch I-Tolerance Support
Health Effects Division (7509C)

THRU: Edward Zager, Acting Chief
Chemistry Branch I-Tolerance Support
Health Effects Division (7509C) *R. Loranger for*

TO: George LaRocca/Adam Heyward, PM Team 13
Insecticide-Rodenticide Branch
Registration Division (7505C)
and
Michael Metzger/Deborah McCall
RCAB/HED (7509C)

Background

Miles, Incorporated is requesting the establishment of tolerances for cyfluthrin ([cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate] on citrus fruits, oil, dried pulp, and molasses at 0.2, 1.0, 1.0, and 0.5 ppm, respectively, in the subject petitions. CBTS cited deficiencies in the initial review of the petition, and this submission contains a response to those deficiencies (see review of S. Willett dated 12/5/94).

Tolerances for cyfluthrin have previously been established on several commodities at levels ranging from 0.01 to 4 ppm, and are listed in 40 CFR 180.436. Food and feed additive tolerances of 0.05 ppm have also been established as a result of use of cyfluthrin in food/feed handling establishments and are listed in 40 CFR 185.1250 and 186.1250, respectively.

CBTS recommended for the issuance of a Section 18 allowing use of cyfluthrin on citrus in California in the 1/26/95 memo of S. Willett.



Recycled/Recyclable
Printed with Soy/Candla Ink on paper that
contains at least 50% recycled fiber

Conclusions

- o All residue chemistry data requirements for this petition have been adequately addressed. **PM Please Note:** We have no objection to allowing a regional registration of Baythroid 2EC for use on citrus in California and Arizona only. However, due to the complexities concerning regional registrations of major crops, other OPP factions (e.g. BEAD and RD/RSB) should be consulted (see CBTS comments/conclusions, re: deficiency 2c).
- o As a result of changes in chemistry branch procedures, section 409 (FFDCA) tolerances are not needed for dried citrus pulp and citrus oil. However, since residues are present in these not RTE commodities at levels higher than the section 408 tolerances, section 701 maximum residue limits (MRLs) should be proposed. The petitioner should submit a revised section F proposing section 701 MRLs for cyfluthrin in/on dried citrus pulp and citrus oil at 0.3 ppm. Also, since citrus molasses is no longer considered a significant food/feed item (see Table II 1995), a 409 tolerance is no longer needed for that commodity, and it should be deleted from the Section F (see discussion under Other Considerations).
- o Meat and milk tolerances for cyfluthrin which have previously been established as a result of other agricultural uses are adequate to cover secondary residue levels which are likely to result from this proposed use on citrus.
- o An International Residue Limit Status sheet is attached to this review. There are no CODEX, Canadian, or Mexican MRLs established for cyfluthrin in/on citrus. Therefore, no compatibility problems exist.

Recommendations

With the submission of a revised section F, CBTS could recommend for the establishment of FFDCA section 408 tolerances or section 701 MRLs for cyfluthrin ([cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate] in/on citrus fruits, oil, and dried pulp at levels of 0.2 ppm, 0.3 ppm, and 0.3 ppm, respectively. The citrus oil and dried pulp numbers should be established as section 701 maximum residue limits.

NOTE TO RCAB/SAB: A DRES run can be initiated at this time using the tolerance levels as specified in Recommendations above.

Detailed Considerations

The deficiencies previously outlined in the 12/5/94 review of S. Willett will be restated here for convenience, followed by the

petitioner's response, and comments/conclusions by CBTS.

Deficiency No 2a

The proposed label/section B is unacceptable. The treatment rate specified on the label and the treatment rates in the field trials are different (cf. 0.1 lb ai/A and 1 oz ai/A), and thus the proposed use is not adequately supported (see also conclusion 5a).

Petitioner's Response to Deficiency No 2a

The Agency evaluation included review only of data submitted in the report identified as MRID 430765-02. These data were cited only for fulfilling guideline 171-4(l), processed food. Another report, MRID 430765-01, contained data cited for guideline 171-4(k), crop field trials. The treatment rates utilized in the field trials reported in this study correspond to those of the proposed labeling.

CBTS Comments/Conclusions

The study specified as MRID 430765-01 was apparently not included in the data package which was initially sent to CBTS. We have obtained a copy from the information branch, and the results will be summarized here.

In this study, seven field trials were conducted on oranges, grapefruit and lemons grown in California (2 on oranges; 1 on grapefruit; 1 on lemons) and Arizona (1 each on oranges, lemons and grapefruit). The proposed use of cyfluthrin will be limited by the label to California and Arizona only. One foliar application of BAYTHROID 2EC was applied to citrus trees at an application rate of 1.6 oz ai/acre (1X as specified on the proposed label). Applications were made using air-blast equipment by spraying each side of the tree row. Whole, mature fruit samples were collected from the four quarters of each tree, high and low areas, and portions exposed and sheltered by foliage at 0, 3, 7 and 14 days following treatment. After harvest, citrus samples were stored frozen until analyzed (≤ 305 days). Data have been previously reviewed to suggest that residues would remain stable during storage (see 5/6/95 memo of J. Garbus, PP No. 3F4309/3H5686).

Residue levels in citrus were determined using methodology previously described (see 12/5/94 memo of S. Willett), which is similar to the enforcement method. Residue levels were quantified using GC/ECD. The detector response was determined to be linear over an appropriate concentration range (0.005 to 0.2 ppm). Orange samples fortified at 0.01, 0.02 and 0.05 ppm were analyzed prior to the analysis of field trial samples, and recoveries ranged from 92 to 110%. Additionally, concurrent recoveries were conducted in each sample set at fortification levels of 0.01, 0.05, 0.1, 0.2,

cyfluthrin 4

0.5 and 1.0 ppm. Recoveries for these samples ranged from 73 to 110%. A summary of the residue data is presented in the table that follows (see also page 17 of report).

TABLE 1: RESIDUES OF CYFLUTHRIN IN FIELD TREATED CITRUS

COMMODITY	LOCATION	VARIETY	PHI	GROSS RESIDUE LEVEL, PPM ¹
GRAPEFRUIT	AZ	MARSH	0	0.05
	CA	MARSH	0	0.04
	AZ	MARSH	3	0.11
	CA	MARSH	3	0.02
	AZ	MARSH	7	0.06
	CA	MARSH	7	0.02
	AZ	MARSH	14	0.03
	CA	MARSH	14	0.02
LEMONS	AZ	LISBON	0	0.05
	CA	LISBON	0	0.08
	AZ	LISBON	3	0.02
	CA	LISBON	3	0.10
	AZ	LISBON	7	0.10
	CA	LISBON	7	0.10
	AZ	LISBON	14	<0.01
	CA	LISBON	14	0.08
ORANGES	AZ	NAVEL	0	0.03
	CA/1	NAVEL	0	0.05
	CA/2	VALENCIA	0	0.05
	AZ	NAVEL	3	0.02
	CA/1	NAVEL	3	0.04
	CA/2	VALENCIA	3	0.05
	AZ	NAVEL	7	0.0
	CA/1	NAVEL	7	0.03
	CA/2	VALENCIA	7	0.04
	AZ	NAVEL	14	0.02
	CA/1	NAVEL	14	0.03

	CA/2	VALENCIA	14	0.05
--	------	----------	----	------

1 Duplicate GC analysis

As the data in the table show, the highest residue, 0.11 ppm, was found in a grapefruit sample taken 3 days after treatment. Sample chromatograms, and raw data were included in the report.

This residue data adequately supports the proposed use. The proposed tolerance of 0.2 ppm on citrus is appropriate. Deficiency 2a is adequately resolved.

Deficiency No. 2b

The Section B/label must be modified to specify a minimum spray volume (per chemistry branch policy).

Petitioner's Response to Deficiency No. 2b

The proposed label has been revised to specify a minimum spray volume of 25 gallons per acre. Copies of the revised label (EPA dated 2/15/95) are included in the submission.

CBTS Comments/Conclusions, re: Deficiency No. 2b

The label is now acceptable. This deficiency is resolved.

Deficiency No. 2c

CBTS typically only approves regional registration requests for minor crops with low dietary intake, and this is not the case with citrus fruits. However, as a result of the 1990 Farm Bill the requirements for regional registrations were expanded to include economic considerations (see 7/7/93 memo of Anne Lindsay re: Policy for Regional Registrations). The present practice within CBTS is to defer to BEAD to make a determination as to whether or not the proposed use can be considered a minor use based on economic considerations. The product manager should go through the appropriate administrative procedures to obtain a formal response from BEAD on this matter.

Petitioner's Response to Deficiency No. 2c

Because the use proposed, control of the single pest citrus thrips, is only applicable to the southwestern states, Miles intends only to market product for this use in the states of California and Arizona. The label has been revised to specify use on citrus in these two states only (see 2/15/95 label). This limitation should adequately address this issue [preceding a determination from BEAD].

CBTS Comments/Conclusions, re: Deficiency No. 2c

Upon informal consultation with knowledgeable Agency personnel and professional contacts, it appears that the citrus thrip is in fact contained to areas in the southwest U.S. at this time. The label restriction against use in areas other than California and Arizona appears to be practical and enforceable, thereby alleviating any residue chemistry/dietary exposure concerns. Although our present field trial guidance requires a total of 23 field trials in support of a citrus crop group tolerances, it seems unnecessary to require additional field trial data from Florida, the major citrus growing region in the U.S., to support this limited use. If the use is modified in the future, additional field trial data will then be required.

From a residue chemistry standpoint, this deficiency is resolved. We have no objection to allowing a regional registration of Baythroid 2EC for use on citrus in the southwest. However, due to the complexities concerning regional registrations of major crops, other OPP factions (e.g. BEAD and RD/RSB) should be consulted.

Deficiency No. 5a

The application rates used in the field trials were lower than the proposed label rate. The petitioner will either need to reduce the label/section B rate to the rates used in the trials (0.4 to 1.0 oz ai/acre), or conduct additional field trials at the higher label rate of 1.6 oz ai/A, equivalent to 0.1 lb ai/A. Regardless of the application rate, additional field trial data may be required if it is determined that a regional registration on citrus is not practical. If it is determined that a regional registration is not appropriate, the registrant should consult EPA Publication No. EPA 738-K-94-001 entitled Pesticide Reregistration Rejection Rate Analysis Residue Chemistry: Follow-up Guidance (June 1994) for the latest guidance on the conducting field trials.

Petitioner's Response to Deficiency No. 5a

See responses under 2a and 2c above.

CBTS Comments/Conclusions, re: Deficiency No. 5a

This deficiency is resolved.

Other Considerations**409 Tolerances**

Due to the issuance of Table II (1995), and internal changes in procedures for reviewing processing studies and determining the need for section 409 tolerances (see 7/17/95 memo of M. Metzger and E. Zager), the proposed food/feed additive tolerances associated with this use on citrus must be revisited. CBTS now uses the highest average field trial (HAFT) residue value instead of the RAC tolerance to determine the need for food/feed additive tolerances. Considering residue values in the 0 and 3 day PHI samples (from table 1 above), the HAFT is 0.06 ppm. Concentration factors were determined to be as follows (see also 12/5/94 memo of S. Willett):

TABLE 2. SUMMARY OF ORANGE PROCESSING DATA

Orange Commodity	Gross Residue ppm	Concentration Factor	Proposed Food/Feed Additive Tolerance
RAC	0.20	---	---
Dried Pulp	1.05	5.3	1.0
Peel	0.23	1.2	0.5
Oil	1.06	5.3	1.0
Molasses	0.58	2.9	0.5
Juice	<0.01	<1.0	---

The typical residues expected in these processed food/feed commodities is determined by multiplying the HAFT by the appropriate concentration factor. The expected residue level in dried pulp and oil would be 0.32 ppm (0.06×5.3).

The next step in chemistry branch procedures is the determination of whether or not food/feed additive tolerances (FFDCA section 409) or maximum residue limits (FFDCA section 701) will be needed. To do this, residue levels in the ready-to-eat (RTE) forms are considered. Dried citrus pulp is not ready-to-eat, and is diluted approximately 3-fold prior to animal consumption. Residue levels in dried citrus pulp as fed to animals is estimated to be 0.11 ppm ($0.32/3$). Similarly, citrus oil is not an RTE commodity is diluted 238-fold prior to consumption. Residue levels are therefore estimated to be $<<0.01$ ppm, which is the limit of detection of the analytical method.

As a result of the new internal procedures, section 409 (FFDCA) tolerances are not need for dried citrus pulp and citrus oil.

However, since residues are present in the not RTE commodities at levels appreciably higher than the 0.2 ppm RAC tolerance, section 701 MRLs should be proposed. The petitioner should submit a revised section F proposing section 701 MRLs for dried citrus pulp and citrus oil at 0.3 ppm.

Also, since citrus molasses is no longer considered a significant food/feed item (see Table II 1995), a 409 tolerance is no longer needed for that commodity, and it should be deleted from the Section F.

Secondary Residues in Meat and Milk

A 2.5 ppm tolerance for milkfat (reflecting 0.08 ppm in whole milk) and a 0.4 ppm tolerance for meat, fat and meat byproducts have already been established for cyfluthrin as a result of previously registered agricultural uses (see 40CFR 180.436). The only animal feed item now associated with this proposed use is dried citrus pulp. It is estimated that dried citrus pulp would comprise no more than 20% of the diet of beef or dairy cattle. The animal dietary burden is estimated at 0.07 ppm $(0.2/0.9 \times 0.3)^1$. The currently established meat and milk tolerances are therefore adequate to cover this use on citrus since they are based on cattle dermal application studies where exposure rates were much higher (see PP No. 1F3923, 4/25/95 memo of G. Kramer).

International Harmonization

An International Residue Limit Status sheet is attached to this review. There are no CODEX, Canadian, or Mexican MRLs established for cyfluthrin in/on citrus. Therefore, no compatibility problems exist.

Attachment: International Residue Limit Status Sheet

cc: RF, Circ., S. Willett, E. Haeberer, PP No. 4F4313/4H5687

7509C:CM2:RM804C:305-6380:SHWillett: shw-3/6/96

RDI: E. Haeberer, 3/8/96: R. Loranger, 3/8/96

¹For the most recent guidance on how animal dietary burden is estimated, consult Pesticide Reregistration Rejection Rate Analysis: Followup Guidance, EPA Document No. 738-K-94-001

Attachment:

Page 1 of 1

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Cyfluthrin

CODEX NO. 157

CODEX STATUS:

☒ No Codex Proposal
Step 6 or Above (on citrus)

Residue (if Step 8): _____

Cyfluthrin per se

PROPOSED U.S. TOLERANCES:

Petition No. 4F4313/4HS687

DEB Reviewer S. W. Helt 3/6/96

Residue: Cyfluthrin *

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
----------------	--------------------------------

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
----------------	--------------------------------

<u>citrus</u>	<u>0.2</u>
<u>citrus oil</u>	<u>1.0</u>
<u>dried citrus pulp</u>	<u>1.0</u>

CANADIAN LIMITS:

☒ No Canadian Limit

Residue: _____

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
----------------	--------------------------------

MEXICAN LIMITS:

☒ No Mexican Limit (on citrus)

Residue: _____

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
----------------	--------------------------------

NOTES

Cyano (4-Fluoro-3-phenoxyphenyl)methyl
3-(2,2-dichloroethenyl)-2,2-dimethyl-
cyclopropane carboxylate

Form Revised 1989



13544



R128438

Chemical: Cyfluthrin

PC Code:
128831

HED File Code: 11000 Chemistry Reviews

Memo Date: 3/11/1996

File ID: DPD213792

DPD213307

Accession #: 412-06-0195

HED Records Reference Center
7/21/2006

